Application No. Applicant(s) PHILLIPS, JEFFREY OWEN 09/481,207 Interview Summary Art Unit Examiner Jane T. Fan 1625 All participants (applicant, applicant's representative, PTO personnel): (1) Jane T. Fan. (3) Dr. Phillips. (2) *Dr. Sharp*. (4) Mr. Mahoney. Date of Interview: 16 July 2001. Type: a) Telephonic b) Video Conference c)⊠ Personal [copy given to: 1) applicant 2) applicant's representative Exhibit shown or demonstration conducted: d) Yes If Yes, brief description: _____. Claim(s) discussed: 23-621. Identification of prior art discussed: PTO-1449. +als 67. 262-264, pat. 5247,918 Agreement with respect to the claims f) was reached. g) was not reached. h) N/A. Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet . (A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.) i) It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked). Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet. PRIMARY EXAMINER **GROUP 1200** Examiner Note: You must sign this form unless it is an

Attachment to a signed Office action.

Examiner's signature, if required



Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

- 1. Claim 23 will read: A solid pharmaceutical dosage form that is not enteric-coated or delayed-released consisting essentially of (a) a therapeutically effective amount of a proton pump inhibitor (PPI) selected from a group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole and leminoprazole; and (b) a buffering agent selected from a group consisting of sodium bicarbonate and potassium bicarbonate in an amount sufficient to prevent or inhibit acid degradation of the PPI by gastric acid so as to achieve bioavailability of at least 75% in comparison to the bioavailability of the enteric-coated or delayed-released solid dosage form. Sharma's comparison is required for showing unexpected improvement in efficacy study.
- 2. Claims 24-25,45-51,54-55, 124-126, 142-143, 164-166, 223-225, 241-242, will be cancelled.
- 3. Claim 44, " or granules" has been added at the end.
- 4. Claims 52, 130, 170, 198, 229, " comprises about 250mg to" will be changed to "is "--
- 5. Claims 53,131,170, 198, 230 "comprises about 840mg" will be changed to " is about 1000mg
- 6. Claim 56 will be made an independent claim. It needs a showing to prove that this particular combination is unexpectedly better than other combination recited in the art.
- 7. Claim 57 will read " A method of producing a liquid pharmaceutical composition by combining the dosage form recited in claim 36 with an aqueous medium."
- 8. Claim 95,"orally" will read "enterally" same will applies to other claims for the word "oral". TD will be required for double patenting rejection over the parent file for claim 95.
- 9. Anticedent basis is required when calcium carbonate is recited.
- 10. Claim 203 will depend on claim 181.
- .11. Claim 238 part (b) will read a second part contacting the enteric coating of the first part.
- 12. Claims 251-252 will be rewritten and using graphs and pictures .
- Other claims will be likewise amended if applicable.
- 13. Applicants will submit a supplemental amendments within 30 days...

